

REMARKS

Claims 1-26 and 38-49 are pending in the present application. Claims 1-43 were presented for examination. Claims 27-37 have been cancelled and claims 44-49 have been added by amendment.

In the office action mailed December 1, 2003 ("the Office Action"), claims 38 and 40 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,074,213 to Hon (the "Hon patent"). Claims 1, 4, 5, 7-10, 12-14, 16, 18, 19, 21-24, 26, 27, 30, 31, and 33-36 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of U.S. Patent No. 5,791,901 to Ramshaw *et al.* (the "Ramshaw patent"). Claims 39 and 41-43 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of U.S. Patent No. 6,321,113 to Parker *et al.* (the "Parker patent"). Claims 2, 6, 11, 15, 20, 25, 28, 32, and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of the Ramshaw patent in further view of the Parker patent. Claims 3, 17, and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of the Ramshaw patent in further view of the Parker patent in further view of U.S. Patent No. 5,645,571 to Olson *et al.* (the "Olson patent").

The Examiner has cited the Hon patent as prior art under 35 U.S.C. 102(e). The Hon patent, however, cannot represent prior art under 35 U.S.C. 102(e) because the present application was filed *after* the date on which the Hon patent issued, namely, June 13, 2000. The present application was filed on December 19, 2000. Consequently, at best, the Hon patent can represent prior art under 35 U.S.C. 102(a). Acknowledgement by the Examiner of Applicant's position with respect to the Hon patent is requested. ✓

As previously mentioned, claims 27-37 have been cancelled by amendment. The rejection of claims 27-37 under 35 U.S.C. 103(a) as being unpatentable over combinations of the Hon, Ramshaw, Parker, and Olsen patents, is now moot in view of the cancellation of these claims. Claims 27-37 have not been cancelled because of the Examiner's rejections and it is inappropriate to infer that the claims have been cancelled for reasons of patentability.

Claims 44-49 have been added to claim alternative embodiments of the invention described in the specification. Support for the subject matter of claims 44-49 can be found in the

specification, including the figures and originally filed claims. No new matter has been added by claims 44-49.

The disclosed embodiments of the invention will now be discussed in comparison to the prior art. Of course, the discussion of the disclosed embodiments, and the discussion of the differences between the disclosed embodiments and the prior art subject matter, do not define the scope or interpretation of any of the claims. Instead, such discussed differences merely help the Examiner appreciate important claim distinctions discussed thereafter.

The present invention includes embodiments directed to systems and methods for providing medical device training for a medical device that includes a user computer coupled to a server through a network. The user computer uses graphical user interfaces to provide a trainee with medical device training information, such as for operating device controls and performing first aid techniques. The graphical user interfaces include various objects that are used to access and navigate through the medical device training information. These objects include training sub-topic objects which can be used to link from one screen to a medical device training information screen, audio and video objects that enable a trainee to initiate the playback of audio and video information that supplements textual medical device training information, and navigation objects that allow a trainee to index through the medical device training screens. The objects further include interactive simulation objects with which a trainee interacts to simulate operation of controls and device instruments of the medical device as part of the training. Additional objects are also described in the present application, however, in the interest of brevity they will not be discussed herein.

The objects of a graphical user interface generate requests to the server, and in response, the appropriate information and data is provided over the network to the user computer. With respect to the interactive simulation object, a feedback request is generated when the trainee interacts with the interactive simulation object. Feedback that indicates whether the trainee's interaction was appropriate or performed correctly is provided in response to the interaction. For example, an embodiment of the present invention is described as having an interactive first aid demonstration object illustrated in a graphical user interface that is used to demonstrate a first aid technique performed with the device for which the trainee is receiving training. As described in the present application, the interactive first aid demonstration object

can solicit interaction from the trainee, such as, the trainee may be requested to manipulate and place simulated medical device first aid instrument objects. In response to the interaction with the simulated medical device first aid instrument object, feedback indicating whether the trainee's interaction was proper or performed correctly is provided to the trainee. Through the use of the interactive simulation objects, as well as other objects, medical device training can be facilitated through the trainee's interaction with the medical device.

Rejection of claims 38 and 40 under 35 U.S.C. 102(a) as being anticipated by the Hon patent.

Claim 38 is patentably distinct from the Hon patent because the Hon patent fails to disclose the combination of limitations recited by claim 38. The Hon patent describes a system for training teams where the team members can be located at different locations having respective remote stations. Each remote station includes various input devices that allow a team member to provide "differentiated input" during a training exercise. That is, each team member can provide input different than any other team member as part of the training exercise. The input devices are described in the Hon patent as providing singular psychomotor performance input that is critical to the team activity. *See* col. 4, lines 61-64. Moreover, the input devices are described as having more or less fidelity of appearance and operation in full reality, and simulate performance in terms of, among other things, timing, pressure, and analog movement. *See* col. 4, lines 64-67. Each remote station is also capable of receiving differentiated feedback that is based on the user's interaction with the particular input device as well as another team member's interaction with the input device at the different remote station. With the differentiated input and feedback provided by the system described in the Hon patent, team members can attend to their respective activity unobserved by any other team member, but yet contribute to the overall simulated team activity. Thus, team members can train at different remote stations under real-time conditions that simulate a team coordinated effort.

Claim 38 recites, in pertinent part, a method for providing instructional information on the use of a medical device to a user computer, the method comprising providing a medical device control object in a first graphical user interface, providing a medical device first aid instrument object in the first graphical user interface or a second graphical user interface, and

providing feedback in response to interacting with the medical device control object and medical device first aid instrument object indicative of the correctness of the interaction with the medical device control object and the medical device first aid instrument object.

The Hon patent fails to disclose the combination of limitations recited by claim 38. For example, the Hon patent fails to disclose providing either a medical device control object or a medical device first aid instrument object in a graphical user interface. As described in the Hon patent, team member interaction is with unique devices designed for psychomotor performance input that are attached to the remote stations. Interaction with the interactive simulation objects included in a graphical user interface, as recited in claim 38, is not disclosed in the Hon patent. Moreover, the teaching of the Hon patent would not be modified for interaction with interactive simulation objects included in graphical user interfaces because interaction with the input devices is necessary to demonstrate appropriate psychomotor input in the correct manner and at the correct time. As described in the Hon patent, demonstrating appropriate psychomotor input is one of "at least six unique aspects" of the invention. *See* col. 8, lines 60-61 and col. 9, lines 13-37. Additionally, the Hon patent fails to teach providing feedback in response to interacting with the medical device control object and medical device first aid instrument object indicative of the correctness of the interaction with the medical device control object and the medical device first aid instrument object. As acknowledged by the Examiner, the Hon patent "does not specifically disclose that the feedback is used to indicate the correctness of the use of the medical device or whether a particular interaction is appropriate under given conditions." *See* the Office Action at page 4.

For the foregoing reasons, claim 38 is patentably distinct from the Hon patent. Similarly, claim 40 is patentably distinct from the Hon patent based on its dependency from claim 38. That is, dependent claim 40 further narrows the scope of claim 38 from which it depends, and consequently, if a claim is dependent from an allowable base claim, the dependent claim is also allowable. Therefore, the rejection of claims 38 and 40 under 35 U.S.C. 102(a) should be withdrawn.

Rejection of claims 39 and 41-43 under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of the Parker patent.

The Examiner has cited the Parker patent as teaching that “for a good networked connection at a remote site from the main analysis computer as Automated External Defibrillator is preferred.” See the Office Action at page 7 (citations omitted). The Examiner further characterizes the Parker patent as teaching that “both graphical and textual data of interest to the medical use in progress may be represented on a single screen for use of medical practitioners.” See the Office Action at page 8 (citations omitted).

Without addressing whether the Examiner’s characterization of the Parker patent is accurate, even if it is assumed that the Parker patent teaches the subject matter described by the Examiner, the Parker patent fails to make up for the deficiencies of Hon patent, as previously discussed with respect to claims 38 and 40. That is, the Parker patent does not describe or suggest providing either a medical device control object or a medical device first aid instrument object in a graphical user interface. The Parker patent further fails to disclose providing feedback in response to interacting with the medical device control object or the medical device first aid instrument object. Moreover, claims 39 and 41-43, which depend from claim 38, are also patentable based on their dependency from allowable claim 38.

For the foregoing reasons, claims 39 and 41-43 are patentable over the Hon patent in view of the Parker patent, and therefore, the rejection of claims 39 and 41-43 under 35 U.S.C. 103(a) should be withdrawn.

Rejection of claims 1, 4, 5, 7-10, 12-14, 16, 18, 19, 21-24, and 26 under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of common and well known practice, and additionally, in view of the Ramshaw patent.

The Examiner has argued that utilizing “a feedback loop for informing users as to the correct use of any device in which feedback has been implemented” is a common and well-known practice. See the Office Action at page 4. However, the Examiner’s statement that utilizing a feedback loop is common and well-known is unsubstantiated. The Examiner has failed to provide any evidentiary support in the record of this fact. The Examiner has also cited the Ramshaw patent. However, as stated by the Examiner, the Ramshaw patent is cited “[i]n

addition” to the Examiner’s reliance on the “common and well-known practice” of utilizing a feedback loop. As stated in the Manual of Patent Examining Procedure (the “MPEP”), when an Examiner has taken official notice of a fact unsupported by documentary evidence, “the basis for such reasoning must be set forth explicitly.” *See* MPEP, 2144.03(B). No such reasoning has been provided by the Examiner in the present case. Moreover, according to the MPEP, “[i]t is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence upon which a rejection is based.” *See* MPEP, 2144.03(E). That is, the fact for which official notice has been taken should “serve only to ‘fill in the gaps’ in an insubstantial manner.” *Id.* The Examiner has not limited his reliance on the “common and well-known” utilization of a feedback loop to merely “fill the gaps,” as prescribed by the MPEP. On the contrary, the Examiner has inappropriately relied on the assertion of fact characterized as common and well-known as principal evidence in rejecting the claims. Consequently, unless the Examiner can provide specific factual findings predicated on sound technical and scientific reasoning to support the conclusion of common knowledge, or alternatively, provide documentary evidence, the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of the common and well-known fact asserted by the Examiner must be withdrawn.

As previously mentioned, the Examiner has also cited the Ramshaw patent in supporting a rejection of the claims under 35 U.S.C. 103(a). The Examiner has characterized the Ramshaw patent as teaching a “network connected interactive medical training system for teaching students how to use medical devices in which a student is presented with selection of instruments for use in a particular procedure step and will rerequest the information on instrument use until the user enters [sic] the appropriate answer where the answer is the appropriate instrument for use in that particular step of the procedure under the conditions pertaining in the simulated procedure.” *Id.* The Examiner argues that it would have been obvious to combine the Hon and Ramshaw patents in order to “extend an existing feedback information stream to include informing users as to the correct use of a medical device as disclosed by Hon.” *Id.*

Claims 1, 14, and 26 are patentable because the combined teachings of the Hon patent and the Ramshaw patent fail to teach or suggest the combination of limitations recited by claims 1, 14, and 26.

As previously discussed with respect to the rejection of claims 38 and 40, the Hon patent fails to disclose including at least one interactive simulation object with which interaction simulates operating controls or device instruments of the medical device. The Ramshaw patent fails to make up for the deficiency of the Hon patent. That is, the interactive simulation objects as recited in claims 1, 14, and 26 are not taught by the Ramshaw patent. Moreover, generating feedback as recited in claims 1, 14, and 26, that is, in response to interacting with the interactive simulation object, is not described in the Ramshaw patent as well.

The Examiner has characterized the Ramshaw patent as teaching how to use a medical device by presenting a student with the selection of instruments for use in a particular procedure step and providing feedback by continuing to request selection by the student until the correct instrument is selected. *See* the Office Action at page 4. However, selecting the correct instrument from a selection of presented instruments is not analogous to interacting with a interactive simulation object, or providing feedback in response to the interaction that indicates whether the particular interaction is appropriate and the correctness on the use of the medical device. As recited in the claims, interaction with the interactive simulation object “simulates operating controls or device instruments of the medical device.” *See* claims 1, 14, and 26. As with the Hon patent, the Ramshaw patent does not disclose any interactive simulation objects as recited in the claims. At most, the Ramshaw patent describes providing visual representations of various instruments for selection by a student. The selection of one of the various instruments, however, does not simulate operating controls or device instruments of the medical device.

Additionally, the feedback discussed in the Ramshaw patent is not analogous to the feedback provided in response to interacting with the interactive simulation object that indicates whether the particular interaction is appropriate and the correctness on the use of the medical device. In the Ramshaw patent, the correctness of the selection of the instrument is merely provided to the student. As previously discussed, there is no interaction described in the Ramshaw patent that simulates operation of controls or device instruments of the medical device. Consequently, the “feedback” described in the Ramshaw patent, that is, continually requesting

selection of a instrument until the correct one is selected, does not indicate whether a particular *interaction* is appropriate or the *correctness on the use* of the medical device, as recited in claims 1, 14, and 26.

For the foregoing reasons, claims 1, 14, and 26 are patentable over the Hon patent in view of the Ramshaw patent. Claims 4, 5, 7-10, 12, and 13, which depend from claim 1, and claims 16, 18, 19, and 21-24, which depend from claim 14, are similarly patentable based on their dependency from a respective allowable base claim. Therefore, the rejection of claims 1, 4, 5, 7-10, 12-14, 16, 18, 19, 21-24, and 26 under 35 U.S.C. 103(a) should be withdrawn.

Rejection of claims 2, 6, 11, 15, 20, and 25 under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of the Ramshaw patent in further view of the Parker patent and the rejection of claims 3 and 17 under 35 U.S.C. 103(a) as being unpatentable over the Hon patent in view of the Ramshaw patent in further view of the Parker patent in further view of the Olson patent.

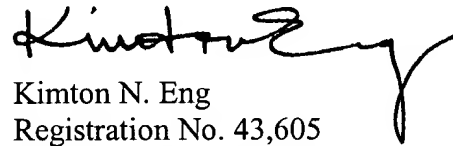
The previous discussion with respect to the Hon and Ramshaw patents similarly applies to the rejection of claims 2, 3, 6, 11, 15, 17, 20, and 25. Additionally, the Examiner has cited the Parker patent and Olsen patents in supporting the rejection of the claims. The Olsen patent has been cited by the Examiner as teaching “an AED that has self-diagnostic capability as well as providing troubleshooting and device maintenance indicators and instructions (Figs 3 and 4).” See the Office Action at page 10, paragraph 7. The Parker patent has been cited by the Examiner for the teaching the subject matter as previously discussed with respect to the rejection of claims 39 and 41-43. Without addressing the accuracy of the Examiner’s characterization of the Parker and Olsen patents, neither patent makes up for the deficiencies of the Hon and Ramshaw patents as previously discussed, alone or in combination. That is, neither the Parker nor Olsen patent describes or suggests providing an interactive simulation object in a graphical user interface as recited in the claims, or providing feedback in response to interacting with the interactive simulation object. Additionally, claims 2, 3, 6, and 11, which depend from claim 1, and claims 15, 20, and 25, which depend from claim 14, are also patentable based on their dependency from a respective allowable base claim. Therefore, the rejection of claims 2, 3, 6,

11, 15, 17, 20, and 25 under 35 U.S.C. 103(a) as being unpatentable over combinations of the Hon, Ramshaw, Parker, and Olsen patents, should be withdrawn.

All of the claims pending in the present application are in condition for allowance. Favorable consideration and a timely Notice of Allowance are earnestly solicited.

Respectfully submitted,

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Enclosures:

Postcard

Fee Transmittal Sheet (+ copy)